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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/538,396	03/29/2000	Pramod B. Mahajan	1116	6440

27310 7590 08/27/2003

PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/27/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/538,396

Applicant(s)

MAHAJAN ET AL.

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8, 12, 14 and 18-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8, 12, 14, and 18-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed on 6/13/03 in reply to the Office action of 1/13/03 has been entered. Claims 2-8, 12, 14 and 18-38 are pending and are under consideration.

All previous rejections and objections not set forth below have been withdrawn. The rejection under 35 USC 101 has been withdrawn in- part as Rad50 polynucleotide is now considered to have utility. The rejection under 112. 1st paragraph is maintained for the reasons set forth below.

Claim Rejections - 35 USC § 112

2. Claims 2-8, 12, 14, 18-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons of record as set forth in the Office action of 1/13/03. Applicant's arguments filed 6/13/03 have been considered but are not deemed persuasive.

Applicant's arguments are basically the following: 1) since Rad50 is known to be involved in DNA repair and homologous and non-homologous recombination, one skilled in the art who reads to the instant specification would know how to use SEQ ID NO: 1 encoding SEQ ID NO: 2. Applicant asserts that by modulating the level of Rad50

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protein, one can modulate the integration of desired polynucleotides into the genome of a plant cell. Applicant requests that the rejection be withdrawn (response, pages 12-16).

These arguments are not persuasive for the following reasons: firstly, DNA repair and synthesis processes are complex phenomena involving numerous interacting proteins and enzymes, many of which have not yet been identified in plants as evidenced by Applicant's own disclosure. Secondly, while Mre11/Rad50/Xrs2 complex has been implicated in meiotic DNA double strand breaks (DSB) formation in yeast, the specific a role of Rad50 protein in DNA repair process in plants is not yet known. Thirdly, since the plant already contains Rad50 polynucleotide/protein, it is unclear what is the agronomic benefit of a transgenic plant with increased/reduced (modulated) level of Rad50 protein. Fourthly, it is unclear how a modulate level of the Rad50 protein would affect the DNA repair process or integration of desired polynucleotide into the genome of a plant, since other proteins such as Mre11 and Xrs2 are also involved. Therefore, weighing all the factors above and in the last Office action, one skilled in the art would not be able to use SEQ ID NO: 1 and sequences that hybridize thereto, and sequences having at least 90% and 95% sequence identity to the disclosed sequences and having role in double-strand DNA break repair to produce a transgenic plant with modulated level of Rad50 protein, without undue experimentation. Further, one skilled in the art would not know how to use a transgenic plant with modulated level of Rad50 protein, as stated in the last Office action. Therefore, the rejection is maintained.

Written Description

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Claims 2-8, 12 and 14, 20, 23-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the Office action of 1/13/03. Applicant's arguments filed 6/13/03 have been considered but are deemed persuasive.

Applicant argues that the claimed polynucleotide sequences having at least 90% sequence identity to SEQ ID NO: 1, polynucleotides encoding a polypeptide having at least 90% sequence identity to SEQ ID NO:2, and polynucleotides that hybridize to SEQ ID NO:1 under the specified hybridization conditions and encoding a polypeptide involved in double-strand DNA break repair, and transgenic plant/plant cell/seed are adequately described. Applicant relies upon the following points to support this position: 1) 90% identity or hybridizing property as recited in the claims is a predictable structure of the sequences encompassed by the claimed invention; 2) conserved domains and multiple sequence alignment of SEQ ID NO: 2 with known Rad50 proteins have been provided. Applicant cites Example 14 of the Revised Interim Written Description Guidelines directed to a generic claim, to support this position.

These arguments are not persuasive for the following reasons: 1) Applicant has not described a representative sample of the genus of the claims because SEQ ID NO: 1 and 2 do not provide adequate written description for any and all polynucleotides/polypeptides having at least 90% sequence identity to SEQ ID NO: 1

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and 2, and all polynucleotides that hybridize to SEQ ID NO:1. The disclosed conserved domains are not unique to Rad50 proteins but are common to all DNA repair proteins, and do not constitute a substantial portion of the genus of the claims. With respect to Example 14 of the Revised Interim Written Description Guidelines, it is noted that the example is not applicable in this case because claims drawn to polynucleotides having 95% sequence identity are not rejected in this Office action. Therefore, in view of the above and in the last Office action, the claimed invention is not adequately described.

Remarks

A nucleic acid sequence of SEQ ID NO: 1 and nucleic acid sequences encoding SEQ ID NO: 2 are free of the prior art of record.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

8/20/03

Mai

A handwritten signature in black ink, appearing to read "Amy Nelson", with a long horizontal flourish extending to the right.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600